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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,296	03/27/2004	Xing Fa Wang	XLH8FW	1034
35673	7590	03/21/2006	EXAMINER	
XING FA WANG 16 PALM STREET WORCESTER, MA 01604-3844			SIMS, JASON M	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/810,296	Applicant(s) WANG, XING FA	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112- First

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The MMA.exe computer program is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). It is improper to incorporate by reference essential subject matter.

The attempt to incorporate subject matter into this application by reference to MMA.exe is ineffective because it does not enable one skilled in the art to practice the claimed invention.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must be able to determine normal range of values for all of the atherosclerotic parameters. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The description describes papers, which have come out with guidelines that have defined acceptable levels for some of the parameters. For example, the LDL and CRP parameters have disclosed ranges of levels and have a corresponding disease risk level based on this range. The description does not provide detailed guidance as to the actual acceptable range of values used for all of the atherosclerotic parameters or the corresponding disease risk levels for all

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of the atherosclerotic parameters. For example, the radius of arterial vessels and axial positions are two additional parameters used to assess CHD risk.

However, "it can be concluded that the morphology of the vertbro-basilar junction as well as the morphology of the basilar artery is very variable amongst adults."

(Ravensbergen et al.) What is the acceptable range of normal values of arterial vessels and axial positions? In addition, the inventor states that, "no screening method is able to determine the contribution of the arterial geometry to the disease." (Wang et al.) With regards to those parameters disclosed,

"observations suggest that the most recent National Cholesterol Education Program Adult Treatment Panel III guidelines, with LDL-C targets of 2.6 mmol/L, may result in under-treatment of a significant number of patients." (Evans et al.)

Therefore, what is the acceptable range of LDL levels that would be considered normal and address this problem. Additionally, "many individuals who have CHD do not have substantially elevated LDL-C but have derangement of other lipid fractions." (Ballantyne et al.)

c) The description provides working examples of identification of connectron symmetries in genomic sequences. The description does not provide working examples of using identified connectron symmetries to predict effects on gene expression.

d) The nature of the invention, CHD diagnosis, prediction, or treatment, is complex.

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e) The prior art does show a high level of unpredictability with regards to the parameters, a, z, and alpha. In addition, the prior art shows a high level of unpredictability with regards to detecting CHD based on LDL levels.

f) The skill of those in the art of CHD prediction and treatment is high.

g) The predictability of the relationship between some of the atherosclerotic parameters and CHD is unknown in the prior art.

h) The claims are broad in that they are drawn to diagnosing, preventing, or treating CHD.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that all the atherosclerotic parameters can be used to diagnose, prevent, or treat CHD. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not disclose detailed guidance for a range of values for all the atherosclerotic parameters. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between the parameters and diagnosis, prevention, or treatment. Such, amounts to undue experimentation.

Claim Rejections - 35 USC § 112- Second

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the normal" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the measured values" in line 25. There is insufficient antecedent basis for this limitation in the claim.

In claim 1, parameters v and u are vague and indefinite as to their precise meaning. Claim 1 recites the parameters of v and u as being "the variables related to said p and said a." However, the relationship between these parameters remains unclear and is deemed vague and indefinite. Therefore, clearer claim wording is required.

In claim 1, parameters A, B, and E are vague and indefinite as to their precise meaning. Claim 1 recites the parameters of A, B, and E as being "the variables that are independent of said atherosclerotic parameters." However, the values of these parameters or what determines their values remains unclear and is deemed vague and indefinite. Therefore, clearer claim wording is required.

In claim 1, the parameter g has no specific units and therefore is not clearly defined and remains vague and indefinite. Clearer claim wording is required.

In claim 1, the parameter a, the radius parameter of arterial vessels, is vague and indefinite with regards to where this measurement or parameter value is obtained along the arterial pathway. In addition, the parameter alpha, the

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angle parameter of arterial vessels in degree and z, the axial position of diffusional flux are also vague and indefinite with regards to where this measurement or parameter value is obtained along the arterial pathways.

Therefore, clearer claim wording is required.

Claims 2-18 are rejected due to their dependence from a rejected claim and including issues from claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel can be reached via telephone (571)-272-0718.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)-272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER